



UNITED STATES PATENT AND TRADEMARK OFFICE

8/17
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,206	02/28/2002	Yi Li	PF191D1C1	6254
22195	7590	07/16/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			ULM, JOHN D	
		ART UNIT	PAPER NUMBER	
		1646		

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/084,206	LI ET AL.
	Examiner John D. Ulm	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 May 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18 and 21-91 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-91 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/7/04.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

- 1) Claims 18 and 21 to 91 are pending in the instant application.
- 2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Claim 18 stands withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 13 November of 2003.
- 5) Claims 21 to 91 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for those reasons of record in section 4 of the previous office action. As stated therein, the instant application does not disclose a specific biological role for protein of the instant invention or its significance to a particular disease, disorder or physiological process which one would wish to manipulate for a desired clinical effect. Applicant has traversed this rejection on the premise that "the application does disclose a specific biological role for the protein and a significance to a particular disease state", at "for example, page 24, paragraphs [0085] through [0087]". The text referred to by Applicant asserts that:

"[0086] For example, compounds which activate the G-protein may be employed for therapeutic purposes, such the treatment of asthma, Parkinson's disease, acute heart failure, hypotension, urinary retention, and osteoporosis.

[0087] In general, compounds which inhibit activation the G-protein PAF receptor may be employed for variety of therapeutic purposes, example, the treatment of hypertension,

angina pectoris, myocardial infarction, ulcers, asthma, allergies, benign prostatic hypertrophy and psychotic and neurological disorders, including schizophrenia, manic excitement, depression, delirium, dementia severe mental retardation, dyskinesias, such as Huntington's disease Gilles dila Tourett's syndrome, among others. Compounds inhibit G-protein PAF receptors have also been useful reversing endogenous anorexia and the control of bulimia." This argument has not been found persuasive because, as essentially stated in the original rejection, there is no evidence or sound scientific reading of record that supports a conclusion that a receptor protein of the instant invention plays any specific and substantial role in any of those diseases and disorders listed above.

Applicant has further traversed this rejection on the basis that the Kyaw et al. (DNA Cell Biol., 17:493-500 (1998)) and Im et al. (J. Cell Biol. 153:429-434 (2001)) publications disclose that the protein identified in the instant specification as a G protein-coupled PAF receptor is actually a psychosine receptor "that play as role in the white matter disease Globoid Cell Leukodystrophy (GLD; also known as Krabbe's disease)". It is noted that the instant specification does not appear to have disclosed this critical information. An invention must be patentable at the time that an application is filed. Applicant may not rely upon subsequent discoveries to complete the claimed invention. In the decision *In re Lundberg*, 117 USPQ 190, 1958, the CCPA held that "advantages which are not disclosed in application cannot be urged as basis for allowing claims". It is a mater of law that an invention must have a specific and substantial utility in currently available form (at the time that an application is filed). As stated in the original rejection, the court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966) held that: "[u]nless and until a process is refined and developed to this point- where specific benefit exists in currently available form-there is insufficient justification

for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

Applicant's reliance on *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) is misplaced. That court decision determined that a compound which belonged to a family of compounds known to have anti-tumor activity, which is a common and well established specific and substantial utility for that family of compounds, would be reasonably expected to have anti-tumor activity in light of positive *in vitro* data with respect to that particular compound since that data has proven to be an indicator of anti-cancer activity by other members of that family. The protein of the instant invention does not belong to a family of compounds with a common, well established, specific and substantial utility and there is absolutely no evidence that the claimed protein plays a specifically identified role in any of the diseases or disorders listed in the instant specification. The utility of those members of the receptor family to which the claimed protein in the instant application belongs lies in the knowledge that they modulate a specific physiological activity in response to a specific ligand. Since the instant specification does not credibly disclose the identity of a native ligand for the protein of the instant invention, simply disclosing the fact that a protein of the instant invention is a member of the G protein-coupled receptor family is not particularly useful.

6) Claims 21 to 91 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and

substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7) Claims 21 to 25, 27 to 34, 36 to 44, 46 to 56, 58 to 64, 66 to 72, 74 to 80 82 to 88, 90 and 91 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Mattson et al. patent publication (WO 98/32858, 30 July 1998) for those reasons of record in section 7 of the previous office action.

8) Applicant's arguments filed 07 May of 2004 have been fully considered but they are not persuasive for those reasons given above.

9) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10) This application contains claim 18, which is drawn to an invention nonelected with traverse in the reply filed on 13 November of 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM
PRIMARY EXAMINER
GROUP 1600